



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

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ADMINISTRATIVE  
U.S. ENVIRONMENTAL PROTECTION AGENCY

**MEMORANDUM:**

From: Kevin Sweeney, Senior Entomologist

A handwritten signature in black ink, appearing to read "Kevin Sweeney", with a checkmark at the end.

Date: April 7, 2014

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

The review is a response to the registrant's rebuttal dated February 3, 2014. The original review was completed on December 30, 2013 and included previously completed Tasks 155, 156 and 157. The registrant's rebuttal is with regard to my review of MRID 49170301.

**2517-145**

DP barcode: 417812

Decision no.: 480768

Submission no: 947219

Action code: R340

Product Name: Sergeant's fipronil + etofenprox + methoprene

EPA Reg. No or File Symbol: 2517-145

Formulation Type: cat spot-on

Ingredients statement from the label with PC codes included: 9.8% fipronil, (pc code: 129121); 15% etofenprox (pc code: 128965); and 11.8% s-methoprene (pc code: 105402).

Application rate(s) of product: 0.5 ml

Use pattern: cat spot-on

OCSPP/OPPTS Guidelines: OPPTS 810.3300.

**2517-147**

DP barcode: 417814

Decision no.: 480769

Submission no: 947220

Action code: R340

Product Name: Sergeant's fipronil + etofenprox + pyriproxyfen

EPA Reg. No or File Symbol: 2517-147

Formulation Type: cat spot-on

Ingredients statement from the label with PC codes included: 9.8% fipronil, (pc code: 129121); 15% etofenprox (pc code: 128965); and 2.2% pyriproxyfen (pc code: 105402).

Application rate(s) of product: 0.5 ml

Use pattern: cat spot-on  
OCSPP/OPPTS Guidelines: OPPTS 810.3300.

**2517-148**

DP barcode: 417811

Decision no.: 480767

Submission no: 947218

Action code: R340

Product Name: Sergeant's fipronil + etofenprox

EPA Reg. No or File Symbol: 2517-148

Formulation Type: cat spot-on

Ingredients statement from the label with PC codes included: 9.8% fipronil, (pc code: 129121); 15% etofenprox (pc code: 128965).

Application rate(s) of product: 0.5 ml

Use pattern: cat spot-on

OCSPP/OPPTS Guidelines: OPPTS 810.3300.

**I. Action Requested:** Review registrant's rebuttal dated February 3, 2014 in response to your review dated December 30, 2013. This response focused on speed of kill claims for all three products. Specifically, the registrant referred to Agency comments and recommendation on review of MRID 49170301.

**II. Background:** Registrant seeks speed of kill claims and is also using the data to support a previous assertion that the addition of a sub-lethal dose of etofenprox to a fipronil based product provides faster speed of kill when compared to fipronil alone. One study was conducted with the adulticide components (fipronil + etofenprox), which are the same in all three formulations. The registrant submitted a rebuttal discussing why these data - in light of other EPA reviews - supports the proposed product claims.

**Note:** copies of primary DER for each product was sent to the registrant. These were the same for the adulticide discussions and copies were prepared for the individual file for each product.

**III. EPA Responses to registrant's rebuttal dated February 3, 2014**

**Study Title:** NO MRID. McNamara, T. 2014. Response to the Agency's Review of MRID 49170301 Dated December 30, 2013. Sergeant's Pet Care Products, Inc., Omaha, NE USA, 36 pp.

C. Response to the Agency's Evaluations – items 2 and 3 (page 6 of 36)

**EPA comment** "2. The references made to the Merial Company and Frontline products are usually not allowed and should be reviewed."

**Sergeant's response:** Sergeant's agrees with the review regarding the references to the Merial Company and Frontline products, and has removed any such references from the label.

**EPA response: concur.**

**EPA comment** "3. Repellency claims: this study does not support repellency claims. Blood feeding status/engorgement was not evaluated nor reported."

**Sergeant's response:** Sergeant's did not propose any repellency claims on the three product labels, nor has Sergeant's included any such claims as part of the label amendments."

**EPA's response:** Sergeant's response is true but the EPA comments addressed repellency to make it clear that these data could not ever support any repellency claims.

**D. Sergeant's Response to the Agency's Evaluations – Item 1 (page 7 of 36)**

EPA comment "1. Remove all speed of kill claims of less than 24 hours for ticks and fleas. This includes 15 minute claims for both pests as well as "Starts killing claims". The data do not support these claims. The fipronil + etofenprox products did not kill any faster than the fipronil only product until Day 7.

a. Remove the following claims where they appear on the three product labels:

- [Starts killing fleas in [as little as] [just] [15 minutes] [after application] ]
- [Starts to kill fleas in[as little as][just][15 minutes][after application]]
- Quickly kills fleas
- Kills fleas fast
- Quickly kills ticks
- Kills ticks fast
- Quickly kills fleas and ticks
- Kills fleas and ticks fast
- [Kills[adult] fleas [starts killing][starts to kill][in as little as] [in just] [15 minutes]
- [Kills newly emerged fleas ([starts killing][starts to kill][in as little as] [in just][15 minutes] before they lay eggs)]

EPA Note: remove "before they lay eggs" from the label.

**Based on the submitted data EPA should consider removing the 1 hour and 4 hours claims from the label. The data do not support these claims. Efficacy was very low at these evaluation intervals with the exception 4 hours post-infestation at 7 days post-treatment. The use and accuracy of hand counting of fleas is also questionable and generally not done in pet product evaluations.**

The remaining label claims proposed by the registrant are acceptable."

**Summary of Sergeant's Response (page 9 of 36)**

"In response to the Agency's review of the efficacy study, MRID 49170301, which was submitted to support additional label claims for:

- Sergeant's Fipronil + Etofenprox + Methoprene Spot On for Cats (EPA Reg. No. 2517-145), containing 9.8% fipronil, 15% etofenprox, and 11.8% S-methoprene;
- Sergeant's Fipronil + Etofenprox + Pyriproxyfen Spot On for Cats (EPA Reg. No. 2517-147), containing 9.8% fipronil, 15% etofenprox, and 2.2% pyriproxyfen; and
  - Sergeant's Fipronil + Etofenprox Spot On for Cats (EPA Reg. No. 2517-148), containing 9.8% fipronil and 15% etofenprox.

Sergeant's agrees to remove any 1 hour and 4 hour killing claims, because the data are not adequate ( $\geq 90\%$ ) for all infestations at these times. **However, Sergeant's is maintaining the "starts killing in as little as 15 minutes" type of claims, because there is currently no EPA guideline that addresses a standard quantitative level to be achieved for these types of claims.** Additionally, Sergeant's data shows significantly more fleas and ticks killed on treated dogs when compared to control dogs, at the 15 minute time intervals. This is also consistent with label language EPA has approved on many other EPA registered pet products. Sergeant's is also maintaining the "fast acting" and "quickly" type claims, because the Agency granted them previously, they are supported by past and current data, and these types of claims are currently on other EPA registered fipronil spot-on products.

**EPA Response:** The agency acknowledges that a statistically significant difference ( $p = 0.05$ ) between untreated control treatments and product treatments is acceptable. EPA agrees and accepts the registrant's rebuttal as described in the summary except for speed of kill where the use of hand counts/area counts was used because is not an accurate means of determining the ectoparasite infestation, especially when the SOP for this procedure was not presented. That being said, the Agency has previously accepted studies using this method (as outlined in detail in the registrant's rebuttal, but it is a policy call by the PM/Branch as to whether or not we can depend on that data now or not. Next, can we depend on these data for studies already completed and used in registration and require more robust studies to evaluate speed of kill in the future?"